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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,630	08/05/2003	Klaus Giese	39078-0005	6369
26633	7590	06/13/2007		
HELLER EHRMAN LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 06/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/633,630

Applicant(s)

GIESE ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-23 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-23, 25-27, 29, 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 04/05/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 10/05/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 04/05/2007, claims 11-23, 25-27, 29 and 31-33 are pending and currently under examination. Applicant has canceled claims 1-10 and 24 and claims 28 and 30 are withdrawn.

### ***Response to Applicant' Arguments***

#### ***Re: Claim Rejections - 35 USC § 112***

The rejection of record mailed 10/05/2006 of claims 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is obviated in response to claim amendments filed 04/05/2007.

#### ***Re: Claim Rejections - 35 USC § 103***

The rejection of claims 11-23, 25-27, 29 and 31-33 under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al. (cited on PTO Form 892

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filed 01/12/2006) in view of Holen et al. (Nucleic Acids Research 04/30/2002) is maintained for the reasons of record in the Office action mailed 10/05/2006.

Applicant's arguments filed 04/05/2007 have been fully considered but they are not persuasive. Applicant argues McSwiggen et al. does not teach a pattern of modified nucleotides. Applicants argue McSwiggen et al. describes modifications of nucleotides based on whether the nucleotide is a pyrimidine or purine, as in Figures 4 and 5 and SEQ ID No. 665 and therefore the resultant nucleotide sequence would produce a random sequence based on the chance occurrence of a certain base in a sequence. Applicants further argue the sequence described by McSwiggen et al. and cited by examiner has an irregular arrangement in terms of composition and length of the modified and non-modified groups and therefore this irregular arrangement cannot be regarded as a pattern. Applicant's arguments are not convincing.

While it is true the nucleotide sequence in Figure 4 of McSwiggen et al. teach the nucleotides are modified with a 2'-O group depending on whether the nucleotide is a pyrimidine, this is not the case with the nucleotide sequences in Figure 5, specifically the cited sequence having SEQ ID No. 665. The sequence having SEQ ID NO. 665 comprises a nucleotide sequence of a sense strand comprising nucleotides "cAuGGcuGccAucuGCGccTT" wherein the lower case nucleotides are 2'-O-Methyl modified nucleotides and the upper case are unmodified nucleotides and this 2'-O-methyl modification is not described as depending on whether the nucleotide is a pyrimidine or purine. Therefore, this sequence comprises a 2'-position modified group that is repeated at least once

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forming a pattern wherein the pattern is, starting from the 5' end: two 2'-position modified nucleotides i.e. groups, wherein this pattern of modified groups is flanked by an unmodified nucleotide on one side.

In response to applicant's argument that the arrangement of nucleotides in the sequence taught by McSwiggen et al. is an irregular arrangement and not a pattern, the pattern disclosed in the specification is not defined such that the pattern can only be formed by a regular nucleotide composition and length of the sequence. Furthermore, the claimed invention is broadly drawn to a ribonucleic acid of any length comprising a double stranded structure *comprising* a repeating pattern of modified groups flanked by an unmodified or differently modified nucleotide and is not drawn to a specific ribonucleic acid molecule comprising a specific number and placement of 2'-O modified nucleotides and a specific number and placement of flanking groups.

Thus, the rejection of record is maintained.

***Re: Claim Rejections - 35 USC § 102***

The rejection of record of claims 11-16 and 21-23 under 35 U.S.C. 102(b) as being anticipated by Crooke et al. (cited on PTO Form 892 filed 01/12/2006) is maintained.

Applicant's arguments filed 04/05/2007 have been fully considered but they are not persuasive. Applicants argue, that a "pattern is a regular arrangement of nucleotides" and the Crooke et al. reference only discloses a nucleotide sequence comprising an arrangement of a "[2'-modification] –

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[ribonucleotide group] – [2'-modification] and this arrangement is not considered a pattern. Applicant's further argue that because examiner states in the last Office action that "the limitation of the flanking groups on one or both sides of a 2'-position modified group is interpreted to mean each 2'-position modified group in a pattern can be separated by one flanking group and that flanking group would therefore flank each 2'-positon modified group on one side", this interpretation by the examiner defines applicant's invention as a pattern is an arrangement such as {[2'-modification] – [flanking group]} – {[2'-modification] – [flanking group]}. Therefore, according to applicant, Crooke et al. cannot anticipate the instantly claimed invention because it does not teach the arrangement as described above. Applicant's argument is not convincing.

First, as stated above, the pattern disclosed in the specification is not defined such that the pattern can only be formed by a regular nucleotide composition and length of the sequence. The claimed invention is broadly drawn to a ribonucleic acid of any length comprising a double stranded structure *comprising* a repeating pattern of modified groups flanked by an unmodified or differently modified nucleotide and is not drawn to a specific ribonucleic acid molecule comprising a specific number and placement of 2'-O modified nucleotides and a specific number and placement of flanking groups. As stated in the previous Office action mailed 10/05/2006 and reiterated herein, the instant claims do not require a repeating pattern of a plurality of modified groups *and* a repeating pattern of flanking groups. The instant claims only require the double stranded structure have a plurality of 2'-position modified groups in a repeating

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pattern and further wherein each 2'-position modified group is flanked on one or both sides by a flanking group wherein the flanking group comprises unmodified or differently modified nucleotides. The nucleotide sequence taught by Crooke et al. teach a sequence having a "[2'-modification] – [ribonucleotide group] – [2'-modification]" arrangement wherein the 2'-position is repeated twice, thus forming the pattern.

In response to applicants assertion that the examiner defined the invention to mean that a pattern is an arrangement such as {[2'-modification] – [flanking group]} – {[2'-modification] – [flanking group]} is incorrect. The explanation of the interpretation of the position of the flanking group was to describe the flanking group taught by Crooke et al. and not to define the invention as the arrangement argued by applicant. As described in the previous Office action, the limitation of the instantly claimed flanking group is interpreted to mean each 2'-position modified group in a pattern can be separated by one flanking group and that flanking group would therefore flank each 2'-position modified group on one side. Thus, the nucleotide sequence taught by Crooke et al. having the arrangement "[2'-modification] – [ribonucleotide group] – [2'-modification]" has a flanking group that flanks each 2'-position modified group and would therefore meet the limitations of the instantly claimed invention.

Thus, Crook et al. anticipates the instant invention.

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The rejection of record of claims 11-19, 21-23, 25-27, 29 and 31-33 under 35 U.S.C. 102(e) as being anticipated by McSwiggen et al. (cited on PTO Form 892 filed 01/12/2006) is maintained for the reasons of record mailed in the previous Office action of 10/05/2006 and as described above in response to applicants arguments of the McSwiggen et al. reference used in the 103 rejection.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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